UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

AMANDA D. HALYCKYJ, Plaintiff, v. MEDTRONIC, INC., Defendant.	Case No. 24-10691 Honorable Laurie J. Michelson

OPINION AND ORDER GRANTING MEDTRONIC'S MOTION TO DISMISS [4] AND GRANTING HALYCKYJ LEAVE TO AMEND HER COMPLAINT

Amanda Halyckyj alleges that after an InterStim medical device manufactured by Medtronic, Inc. was removed from her body, it was tested and found to be defective. She says this defective device injured her. Thus, she sued Medtronic in Oakland County Circuit Court. (*See* ECF No. 1-2.) Medtronic removed the case to federal court (ECF No. 1) and moved to dismiss Halyckyj's complaint (ECF No. 4). For the reasons below, its motion will be granted.

I. Legal Standard

In deciding a motion to dismiss, the Court "construes the complaint in the light most favorable to the plaintiff, accepts the plaintiff's factual allegations as true, and determines whether the complaint 'contain[s] sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.'" *Heinrich v. Waiting Angels Adoption Servs., Inc.*, 668 F.3d 393, 403 (6th Cir. 2012) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). Detailed factual allegations are not required to survive a

motion to dismiss, *HDC, LLC v. City of Ann Arbor*, 675 F.3d 608, 614 (6th Cir. 2012), but a complaint must "raise a right to relief above the speculative level," *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). And the Court need not accept bare legal conclusions. *See Iqbal*, 556 U.S. at 663.

These "basic pleading requirements 'apply to self-represented and counseled plaintiffs alike.'" *Williams v. Hall*, No. 21-5540, 2022 WL 2966395, at *2 (6th Cir. July 27, 2022) (quoting *Harnage v. Lightner*, 916 F.3d 138, 141 (2d Cir. 2019)). Although a *pro se* litigant's complaint is to be construed liberally, *Erickson v. Pardus,* 551 U.S. 89, 94 (2007), that leniency is "not boundless," *Martin v. Overton*, 391 F.3d 710, 714 (6th Cir. 2004). A complaint must "permit the court to infer more than the mere possibility of misconduct." *Iqbal*, 556 U.S. at 679. And the Court cannot "conjure up unpleaded facts to support conclusory allegations." *Williams*, 2022 WL 2966395, at *2 (quoting *Perry v. UPS*, 90 F. App'x 860, 861 (6th Cir. 2004)).

A motion to dismiss "tests the sufficiency of a complaint." *Gardner v. Quicken Loans, Inc.*, 567 Fed. Appx. 362, 364 (6th Cir. 2014). And "it is black-letter law that . . . a court evaluating . . . a motion to dismiss[] must focus only on the allegations in the pleadings." *Bates v. Green Farms Condo. Ass'n*, 958 F.3d 470, 483 (6th Cir. 2020). A plaintiff's response brief to a motion to dismiss, for example, cannot cure a deficient complaint. *Id.* at 483–84 ("Plaintiffs cannot . . . amend their complaint in an opposition brief or ask the court to consider new allegations (or evidence) not contained in the complaint. If a complaint fails to state a claim even under the liberal requirements of the federal rules, the plaintiff cannot cure the

deficiency by inserting the missing allegations in a document that is not either a complaint or an amendment to a complaint." (citations and internal quotation marks omitted)).

II. Background

Halyckyj's pro se complaint is sparse, spanning only two pages and containing many conclusory statements. (ECF No. 1-2, PageID.11.) She alleges that around February 6, 2019, she had "a medical device otherwise known as an InterStim system" implanted into her body. (*Id.* at PageID.11.) The InterStim system was "designed, manufactured, produced[,] and marketed" by Medtronic. (*Id.*) The system was "explanted" from her body on April 29, 2022, at the University of Michigan Medical Center. (*Id.*) It was then "packaged for preservation" and sent to Medtronic under the assumption that "it would remain sealed until the parties agreed upon a protocol for testing." (*Id.*) That testing occurred, and "revealed a defect in the manufacturing process." (*Id.*) That defect caused Halyckj "injury and damages." (*Id.*)

That is the extent of the allegations. There is no specific cause of action identified. Nor does Halyckyj specify what the InterStim device does, what the defect was, or how it injured her. Her response brief, however, sheds some more light on what occurred.

There, Halyckyj explains that she is diagnosed with interstitial cystitis (IC). (ECF No. 13, PageID.72.) IC is a chronic condition that is "part of a spectrum of diseases known as painful bladder syndrome." *Interstitial Cystitis*, Mayo Clinic (Sept. 29, 2021), https://perma.cc/7V4Z-NQYE. IC causes inflammation in the bladder,

leading to bladder pressure, bladder pain, frequent urination, and sometimes pelvic pain. *Id.* The condition can cause severe pain and have a long-lasting impact on quality of life. *Id.* Indeed, Halyckyj says she "suffered years of pain from [this] incurable disease" and tried "all solutions possible for a 'normal life.'" (ECF No. 13, PageID.72.) After other therapies failed, Halyckyj decided to try Medtronic's InterStim system. (*Id.*) She heard "Medtronic . . . [was] the best for health challenges" such as hers. (*Id.*) But after it was implanted, the device began causing Halyckyj "pain with intense shocking whether [she] was laying down for bed, taking a walk[,] or vigorously exercising." (*Id.*) So she ultimately had to have the device removed.

After it was removed, says Halyckyj, the device was tested by a medical lab. (*Id.* at PageID.71.) That testing revealed the "device had only a battery life left of 24-42 months," even though it had only been implanted for 29 months and was marketed to last "5 years at minimum and 10 years at maximum." (*Id.* at PageID.71–72.) The laboratory also determined that the device was "malfunctioning" and "had caused degenerative changes of the bilateral sacroiliac joints and pubic symphysis." (*Id.* at PageID.72.) In other words, it had done "permanent damage[]." (*Id.*)

Despite this painful experience, Halyckyj had another InterStim device implanted after the first was removed. (*Id.*) It appears this device is relieving her IC symptoms and is not causing "the shocking sensation that had crippled [her] with the first device." (*Id.* at PageID.72–73.) The fact that this second device is working properly further convinces Halyckyj that the first was defective. (*Id.*)

Halyckyj seeks damages in excess of $500,000 for her pain, suffering, medical costs, and lost wages. (*Id.* at PageID.73.)

III. Analysis

A. Choice of Law

Halyckyj is a Michigan resident. The device in question was manufactured by a Minnesota company. Halyckyj's claims presumably stem from state tort law. Medtronic analyzes them as negligence and product liability. Thus, at the outset, because the case was removed based on diversity jurisdiction, this Court would typically undertake a choice of law analysis to determine which state's law governs. But that is not necessary here. Medtronic contends that Michigan law applies and Halyckyj does not argue to the contrary. Thus, the Court will follow the parties' lead. Ultimately, however, Halyckyj's complaint fails under either Michigan or Minnesota law.

B. Negligence

As stated, Halyckyj does not identify any causes of action in her complaint or her response brief. Medtronic construes the complaint as alleging negligence and products liability claims and receives no resistance from Halyckyj.[1] (ECF No. 4, PageID.28.)

With respect to negligence, though, Medtronic argues that such a claim is prohibited. (*Id.* at PageID.32.) Medtronic is correct that, under either Michigan or

[1] Indeed, Halyckyj's state case was given an "NP" designation, indicating it involved products liability. *Michigan Trial Court Records Management Standards—Case Type Codes*, Michigan Supreme Court, State Court Administrative Office, 2 (Jan. 2024), https://perma.cc/NRN5-ZB6F.

Minnesota law, Halyckyj's claims merge into a products liability claim. *See Oetjens v. Covidien LP,* No. 22-11220, 2023 U.S. Dist. LEXIS 89025, at *7 (E.D. Mich. May 22, 2023) ("Michigan law forbids plaintiffs from bringing common law negligence claims as separate causes of action in product-liability cases."); *Green Plains Otter Tail, LLC v. Pro-Environmental, Inc.*, 953 F.3d 541, 546 (8th Cir. 2020) ("Minnesota merges negligence and strict liability claims into a single products liability theory, which employs a reasonable-care balancing test to determine whether a product is defective."). So Halyckyj cannot bring a separate claim for negligence.

C. Products Liability

Thus, the question becomes which type of products liability claim Halyckyj is bringing. There are three potential claims under Michigan law: "manufacturing defects, defects due to faulty design, and defects due to inadequate instructions or warnings." *Teal v. Argon Med. Devices, Inc.*, 533 F. Supp. 3d 535, 543 (E.D. Mich. 2021). Minnesota law has similar options. *See SECURA Ins. Co. v. Deere & Co.*, 12 N.W.3d 103, 108 (Minn. Ct. App. 2024) (recognizing separate causes of action for manufacturing defects and design defects); *Marcon v. Kmart Corp.,* 573 N.W.2d 728, 730 (Minn. Ct. App. 1998) (recognizing separate causes of action for design defect and failure to warn).

Halyckyj's claim fits most closely within the manufacturing defect framework. Her complaint alleges that testing on the InterStim device removed from her body "revealed a *defect in the manufacturing* process." (ECF No. 1-2, PageID.11 (emphasis added).) And although the Court cannot consider the factual assertions in her

response as part of her complaint, *see Bates*, 958 F.3d at 483, they seem to confirm that she seeks to assert a manufacturing defect claim. For instance, she says that she "believe[s] that the initial device was in fact defective" in part because she later had a second InterStim device implanted that did not cause the same issues. (ECF No. 13, PageID.72.) Unlike a manufacturing defect, a design defect would have resulted in issues with both of her InterStim devices. *See, e.g.*, *Severstal N. Am., Inc. v. N. Am. Refractories, Co.*, No. 06-10202, 2009 U.S. Dist. LEXIS 48251, at *16 (E.D. Mich. June 9, 2009) ("Unlike a design defect claim, a manufacturing defect claim analyzes whether a *single product* deviated from its intended production." (emphasis added)). And neither her complaint nor response reference inadequate instructions or warnings, so it does not appear that she intended to bring a claim under that theory.[2]

Having narrowed the issue, the Court turns to whether Halyckyj's complaint states a plausible manufacturing defect claim. To make out a prima facie case of defective manufacturing under Michigan law, Halyckyj must establish "(1) that the [InterStim system] was defective; (2) that [it] was defective when it left the control of [Medtronic]; and (3) that the defective [system] caused [her] injuries." *Meemic Ins. Co. v. Hewlett-Packard Co.*, 717 F. Supp. 2d 752, 768 (E.D. Mich. 2010) (citing

[2] Medtronic also argues that if Halyckyj did in fact intend to bring claims for faulty design or inadequate instructions or warnings, those claims are preempted by the Medical Device Amendments to the Food, Drug and Cosmetic Act. (ECF No. 14, PageID.77–78 (citing 21 U.S.C. §§ 337(a), 360k(a); *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001)).) That may be so. But because the Court does not believe Halyckyj intended to bring these claims, and because her complaint fails for other reasons, the Court will not wade into FDA preemption unnecessarily.

Kupkowski v. Avis Ford, Inc., 235 N.W.2d 324, 328 (Mich. 1975)). Minnesota law similarly requires Halyckyj to prove that "(1) [the InterStim system] was in a defective condition unreasonably dangerous for its intended use; (2) the defect existed at the time [it]left [Medtronic's] control; and (3) the defect proximately caused [Halyckyj's] injury." *Duxbury v. Spex Feeds, Inc.*, 681 N.W.2d 380, 393 (Minn. Ct. App. 2004).

Halyckyj's complaint fails under the well-established legal principles that "[a] pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.' Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'" *Iqbal*, 556 U.S. at 678 (citations omitted). Halyckyj alleges only that the product was defective and caused her injuries. But she provides no supporting factual assertions—no factual details to establish her injuries or that the InterStim system was the cause of them. And the complaint contains no factual allegations pertaining to the condition of the device when it left Medtronic. So the complaint cannot survive Medtronic's motion to dismiss.

Recognizing that Halyckyj is pro se and might not appreciate the distinction between facts alleged in the complaint and those asserted in her response brief, the Court will briefly consider the latter as well.

First, while those additional allegations shed more light on the InterStim defect and her injuries, they are still deficient. Halyckyj alleges that the Surgical Pathology Report conducted by the University of Michigan laboratory determined

that the device was "malfunctioning." (ECF No. 13, PageID.72.) But this too is simply a conclusion that lacks the requisite factual support. Halyckyj does say the battery life on the InterStim was lower than she expected. But this is based on a measurement she says was done on July 1, 2021. (ECF No. 13, PageID.71.) That was more than nine months before the device was removed from her body (ECF No. 1-2, PageID.11), and more than 18 months before the lab tested that particular device. (ECF No. 13, PageID.72). Moreover, when measured on July 1, 2021, the device had 24–42 months of battery left. (*Id.* at PageID.71.) Given that the device was implanted February 6, 2019 (ECF No. 1-2, PageID.11), it was measured as having a total battery life of 52–70 months, or 4.3–5.8 years—putting it right around the bottom of the expected battery life of five to ten years (ECF No. 13, PageID.72). Thus, Halyckyj would need to provide greater factual detail in order to adequately plead that the battery was even defective, let alone that this was the defect that caused her injuries.

And, like the complaint, the response brief contains no information about the condition of the InterStim system when it left Medtronic's control or that it reached Halyckyj in the same condition that it was in when it left Medtronic. Without these facts, she cannot plead a viable claim of product liability under either Michigan or Minnesota law. *See, e.g., Oetjens*, 2023 U.S. Dist. LEXIS 89025, at *10; *Marcum v. Depuy Orthopedics, Inc.*, No. 12-834, 2013 U.S. Dist. LEXIS 62875, at *14 (S.D. Ohio May 2, 2013).

IV. Conclusion

In conclusion, Halyckyj's bare-bones complaint fails to state a plausible claim. So the Court GRANTS Medtronic's motion to dismiss. (ECF No. 4.)

But Halyckyj may still be able to plead facts that could survive a motion to dismiss. So the Court will grant Halyckyj 30 days to file an amended complaint that corrects the deficiencies outlined in this order and in Medtronic's motion to dismiss. If Halyckyj does not file an amended complaint by January 16, 2025, her case will be dismissed.

SO ORDERED.

Dated: December 16, 2024

s/ Laurie J. Michelson
LAURIE J. MICHELSON
UNITED STATES DISTRICT JUDGE